REMARKS

This application contains claims 1-41, the status of which is as follows:

(a) Claims 4 and 8 are as originally filed.

(b) Claims 1-3, 5-7, 9, 11-12, and 14-16 have been currently amended.

(c) Claims 10, 13, and 17-20 have been currently canceled without prejudice.

(d) Claims 21-40 were previously canceled by preliminary amendment.

(e) Claim 41 is new.

No new matter has been added. Reconsideration is respectfully requested.

Claim rejections under 35 U.S.C. 102

Claims 1, 3, 5-9, and 17-19 were rejected under 35 U.S.C. 102(b) as being anticipated by US Patent to Bailey et al. While not necessarily agreeing with these rejections, the Applicant has amended claim 1, including adding certain features of claim 10, as discussed hereinbelow, and canceled claims 17-19 to expedite the issuance of a patent on subject matter believed to be allowable.

Claim rejections under 35 U.S.C. 103

Claims 2, 4, and 20 were rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Bailey et al. As discussed below, the Applicant respectfully submits that claim 1, as amended, is allowable, so claims 2 and 4 are also allowable, being of narrower scope than the allowable claim from which they depend. While not necessarily agreeing with the rejection of claim 20, the Applicant has canceled this claim in order to expedite the issuance of a patent on subject matter believed to be allowable.

Claims 1, 3, 5-8, and 10-16 were rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over US Patent Application Publication 2003/0236568 to Hojeibane et al. The Applicant has amended claim 1 to recite that the prosthetic device comprises a prosthetic valve coupled to the downstream

portion of the envelope at the downstream end of the diverging conical section, a feature similar to that originally recited in claim 10.

The Examiner argued that although Hojeibane does not teach a diverging conical section, as recited in claim 1, his device is capable of assuming such a configuration: "when mounted in the annulus the distal end is fully capable of opening wider than the annulus since the aorta is wider and the distal end if [sic] flexible, this is a product by process limitation for which Hojeibane et al is fully capable" (p. 8 of the office action).

The Applicant respectfully submits that the Examiner has failed to make a *prima facie* case of obviousness over Hojeibane et al. Although it may be possible to reshape Hojeibane's device to assume the novel shape recited in claim 1, the mere existence of such a possibility is irrelevant to the patentability of the claim. It would not be obvious to take a device known in the art and reshape it, using impermissible hindsight, based on the teachings of the disclosure of the subject application, without any teaching or motivation to do so in the prior art. The Applicant respectfully submits that Hojeibane provides no motivation to reshape his device, and that the Examiner has not cited any such motivation.

Furthermore, Hojeibane's disclosure focuses on venous valves: "The prosthetic venous valve 100 comprises a structural frame 101 and a biocompatible membrane assembly 102" (paragraph [0040]). Nearly all of the figures, including Figs. 6B, 6C, and 6G cited by the Examiner, show venous valves, as is apparent from their inclusion of at least one of the reference numerals 100, 101, and 102, described as referring to a venous valve. Although Hojeibane mentions that his venous valves techniques may be applied to other non-venous locations, including cardiac valves, such a mention is included in a long list of alternate sites: "Although stent based venous valves are disclosed to illustrate one embodiment of the present invention, one of ordinary skill in the art would understand that the disclosed invention can be equally applied to other locations and lumens in the body, such as, for example, coronary, vascular, non-vascular and peripheral vessels, ducts, and the like, including but not limited to cardiac valves, venous valves, valves in the esophagus and at the stomach, valves in the ureter and/or the vesica, valves in the biliary passages, valves in the lymphatic system and

valves in the intestines" (paragraph [0038]). The Applicant respectfully submits that Hojeibane provides no description or enablement that would enable one of ordinary skill in the art to use his venous valves at these locations, and certainly no suggestion to deform his venous valve into the shape recited in claim 1, for use in an aortic valve, by forcing one end into an aortic annulus for which it was not intended, configured, or properly sized.

In addition, even if Hojeibane's device were to be deformed to provide a diverging conical section, as recited in claim 1, Hojeibane provides no teaching or suggestion that this diverging conical section would cause pressure recovery. The Applicant respectfully submits that those skilled in the art of fluid mechanics can empirically determine whether any given structure will cause pressure recovery, by examining the geometry of the structure. Therefore, the configuration of the recited device to cause pressure recovery represents a definite, structural limitation of the device, and not merely an intended use or physiological effect.

Lastly, a product-by-process claim "is a product claim that defines the claimed product in terms of the process by which it is made" (MPEP 2173.05(p)). In contrast to the Examiner's assertion, claim 1 does not define the prosthetic device by the process by which it is made, and is therefore not a product-by-process claim.

The Applicant further submits that claim 1 is not obvious over the combination of Bailey et al. and Hojeibane et al. In addition to not being suggested by either reference, such a combination would destroy the functionality of Bailey's device. As can be seen for example in Fig. 6A of Bailey, in Bailey's aortic configuration, "distal anchor section 16" covers the ostia of the coronary arteries. Bailey recognized this problem, and provided a solution: "For example, where the stent struts in the distal anchor section 16 would overly an artery branching from the aorta, such as the coronary ostreum [sic] arteries, it may be desirable to either eliminate certain stent struts, or to configure certain stent struts to define a greater interstitial area to accommodate greater blood flow into the coronary ostreum [sic]" (col. 10, lines 18-24). As is well known to those skilled in the art, blood flows into the coronary arteries primarily during diastole. If Hojeibane's downstream valve were to replace Bailey's upstream valve, the valve so

positioned would prevent backflow from the aorta during diastole, and thus deprive the patient of the primary supply of blood flow to the coronary arteries.

Claims 10-12 were rejected under 35 U.S.C. 103(a) as being unpatentable over Bailey et al. in view of European Patent EP 1 469 797 to Figulla et al. As mentioned above, some of the features of claim 10 have been incorporated into claim 1. The Applicant respectfully traverses these rejections. The valve recited in claim 1, as amended, is positioned at a downstream end of the prosthetic device. In contrast, the valve of Figulla et al. is positioned near the center of the prosthetic device, towards the upstream end (as best shown in Fig. 3d). This position is similar to that of the valve in Bailey et al. This important element of claim 1 is thus entirely absent from both Figulla and Bailey.

Claims 2-9, 11-12, and 14-16 directly or indirectly depend from claim 1, and thus are in a condition for allowance, being of narrower scope than the allowable claim from which they depend.

Terminal Disclaimer and Double Patenting

Claims 1-3, 5, 9, and 17-20 were rejected for nonstatutory obviousness-type double patenting over US Patent 7,201,772. While not necessarily agreeing with rejection, the Applicant is filing a terminal disclaimer in order to expedite an issuance of a patent on subject matter believed to be allowable.

Claims 1-3, 5, 13, and 17-20 were provisionally rejected for nonstatutory obviousness-type double patenting over copending Application No. 11/603,912. The Applicant believes that it is premature to file a terminal disclaimer. The present application was filed earlier than the '912 application. If the claims of the present application are found allowable, while the '912 application remains rejectable on other grounds, the Examiner should withdraw this provisional double patenting rejection, and permit the present application to issue as a patent without a terminal disclaimer (MPEP 804 I.B.1).

Claim objections

Claim 1 was objected to because the limitation "the plastic envelope" did not have sufficient antecedent basis. The Applicant has thus amended the claim to delete the word "plastic."

Claim rejections under 35 U.S.C. 112

Claim 6 was rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement, and under 35 U.S.C. 112, second paragraph, as being indefinite, because of the use of the word "forgers." The Applicant has corrected this typographical error, which was inadvertently introduced in the preliminary amendment filed January 5, 2006. The claim as originally filed in the international application of which the present application is the national stage correctly recited "fingers."

Claim 1 was rejected under 35 U.S.C. 112, second paragraph, because the phrase "such as" rendered the claim indefinite because it was unclear whether the limitations following the phrase were part of the claimed invention. Although disagreeing with this rejection, the Applicant has amended claim 1 to recite that the diverging conical section "is configured to produce. . . ." The Applicant respectfully submits that this language removes any potential ambiguity in the claim.

Other claim amendments

Claim 1 has been amended to replace "metal base" with "support." This generalization is broadly supported throughout the specification as filed. Conforming amendments have been made to claims 5, 7, 9, and 16. Claim 41 is new, and recites the "metal base" originally recited in claim 1. Claim 1 has also been amended to generally more positively and clearly recite the elements of the claim and their positions within the device with respect to one another, and to recite that the device comprises a prosthetic valve at its downstream end, as recited in claim 10 as originally filed, and as shown in Figs. 9 and 10 and described in the specification with reference thereto, for example. Claim 1 has further been amended to remove mention of "aortic stenosis" in the preamble, which was in any event non-limiting.

Claims 1-3 and 9 have been amended to replace "proximal" with "upstream," and "distal" with "downstream," in order to more clearly recite these indications of orientation with respect to the direction of blood flow.

Claims 2, 3, 5, 7, 9, and 14-16 have been amended to conform with the amendments to claim 1, and/or to more clearly recite elements of these claims. Claim 5 has also been amended to clarify that the leaflets recited in the first clause are native leaflets, and to generally recite the features of the claim more clearly. Claim 7 has been amended to remove the phrase "at the distal end of the prosthetic device." Claim 11 has been amended to change its dependency in light of the cancellation of claim 10. Claim 12 has been amended to remove "lining the inner surface of the metal base." Claims 14 and 15 have been amended to change their dependencies to light of the cancellation of claim 13.

Objections to the specification

The abstract of the disclosure was objected to because the abstract was over 150 words. The Applicant thus has amended the abstract to appropriately reduce the word count, and to in general reflect the amended language of claim 1.

Other prior art of record

The Applicant has reviewed the prior art made of record and not relied upon, and believes that all of the pending claims are patentable over these references.

The Applicant believes the amendments and remarks presented hereinabove to be fully responsive to all of the grounds of rejection and objection raised by the Examiner. In view of these amendments and remarks, and the filing of the above-mentioned terminal disclaimer, the Applicant respectfully submits that all of the claims in the present application are now in order for allowance. Notice to this effect is respectfully requested.

Respectfully submitted,

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